Remarks

The invention, as defined by pending claims 1, 2 and 5 to 20, provides dosage forms which show increased bioavailability of ophthalmologically active compounds by their provision in a dosage form of an ophthalmic treatment liquid which takes the form of a jet or stream of droplets. As explained below, Applicants respectfully submit that the claimed dosage forms are not obvious over the cited reference, EP 0 224 352.

Rejection Of Claims 1, 2 and 5 to 20 Under 35 U.S.C. § 103(a) Over EP 0 224 352

The Action has rejected claims 1, 2 and 5 to 20 as allegedly being obvious over EP 0 224 352. The Action alleges that the dosage form of the '352 reference differs from the claimed dosage form in droplet diameter and discharge velocity and that it allegedly would have been obvious for a person skilled in the art to use the teachings of this reference to arrive at the claimed invention. While the Action has considered our previously submitted data, it alleges that there is no evidence of record which directly compares the claimed dosage forms with the dosage form of the '352 reference. The Action further alleges that the previously submitted data, which demonstrates the unexpected superior results of the claimed dosage forms over the dosage form of the '352 reference, allegedly is not commensurate with the claimed invention. Applicants respectfully disagree.

Applicants have previously provided evidence of the greater bioavailability of the claimed dosage forms over the dosage form of the '352 reference. This data demonstrated that for both vasoconstriction and mitotic response of the eye, the claimed dosage forms are unexpectedly superior to the dosage form of the '352 reference. While the experiments in the present application and in the '352 reference, compared dosage forms to data generated by instillation of eye-drops, direct comparison of the claimed dosage forms and the dosage form of the '352 reference may be made. In particular, for the same mydriatic response, the dosage form of the '352 reference requires 1.4 times the amount of ephedrine (350 µg vs. 250 µg) compared to the claimed dosage forms. Similarly, for the same miotic response, the dosage form of the '352 reference requires almost 3 times the amount of pilocarpine (140 µg vs. 50 µg) compared to the claimed dosage forms.

Moreover, the claimed dosage forms are not limited to a couple of ophthalmically active ingredients as suggested by the Action. While ephedrine hydrochloride and pilocarpine hydrochloride are ophthalmically active ingredients, one of ordinary skill in the art would know that other ophthalmically active compounds would be made more bioavailable in the claimed dosage forms than in the dosage form of the '352 reference or in eye-drops. Applicants have provided a detailed listing of other ophthalmic treatment liquids that may be used in the claimed dosage forms beginning at paragraph [0044] to paragraph [0063]. Applicant's respectfully request reconsideration and removal of this rejection.

A request for continued examination (RCE) is included with this submission. A petition for a two month extension of time as set forth in 37 CFR §1.136(a) and the fee set in §1.17(a) for a non-small entity is also included with this submission.

Respectfully submitted,

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